



Atty. Dkt. No. 051091-1001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Chen, Chun-Ming et al.
Title: METHOD AND APPARATUS FOR
CONCURRENTLY DETECTING
PATHOGENIC ORGANISMS AND
ANTIMICROBIAL
SUSCEPTIBILITY
Appl. No.: 08/942,369
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Examiner: M. Moran
Art Unit: 1631

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RESPONSE TO OFFICE ACTION

Commissioner for Patents
Washington, D.C. 20231

Sir:

This communication is responsive to the Office Action dated March 27, 2002, concerning the above-referenced patent application. The Applicants gratefully acknowledge courtesies extended to the Applicant at the Examiner's Interview held on September 10, 2002.

Amendments

Please add new claims 32-43. These new claims are introduced solely for the purpose of obtaining early allowance of clearly allowable subject matter and not for any other reason. After these amendments, claims 20-24, 26 and 31-43 are pending in the case.

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32. (New) A method of detecting the presence of urinary pathogens in a biological sample and of simultaneously determining the susceptibility of the urinary pathogens to antimicrobial agents, said method comprising:

providing a multicompartment assay device comprising:

at least one compartment comprising a medium capable of sustaining growth of total microbial organisms; at least one compartment comprising a uropathogenic specific medium comprising a methyl-umbelliferyl substrate; and, at least one compartment comprising an antimicrobial susceptibility interpretation medium;

placing a portion of the biological sample respectively in said at least one compartment comprising a medium capable of sustaining growth of total microbial organisms; said at least one compartment comprising a uropathogenic specific medium comprising a methyl-umbelliferyl substrate; and, said at least one compartment comprising an antimicrobial susceptibility interpretation medium comprising an antimicrobial agent;

whereby metabolism of a signal generating substrate and production of a detectable signal in said at least one compartment comprising a medium capable of sustaining growth of total microbial organisms indicates the presence of microbial organisms in the sample; metabolism of a methyl-umbelliferyl signal generating substrate and production of a detectable signal in said at least one compartment comprising a uropathogenic specific medium indicates the presence of urinary pathogens in the sample; and metabolism of a signal generating substrate and production of a detectable signal in said at least one compartment comprising an antimicrobial susceptibility interpretation medium indicates that the organisms lack susceptibility to the antimicrobial agent comprised in said antimicrobial susceptibility interpretation medium; and

examining the compartments to determine the presence of urinary pathogens in said biological sample and the susceptibility of said urinary pathogens to said antimicrobial agents.

33. (New) The method of claim 32, wherein the biological fluid is urine.

34. (New) The method of claim 33, wherein the urinary pathogens are primary gram negative urinary pathogens.

35. (New) The method of claim 34 wherein the primary gram negative urinary pathogens comprise *Enterobacteriaceae*.

36. (New) The method of claim 34 wherein the primary gram negative urinary pathogens are selected from the group consisting of: *Escherichia coli*, *Klebsiella spp.*, *Enterobacter spp.*, *Proteus mirabilis*, *Proteus vulgaris*, *Morganella morganii*, *Providencia retteri*, and *Acinetobacter spp.*

37. (New) The method of claim 32 wherein the at least one antimicrobial susceptibility interpretation medium comprises amoxicillin, clavulanic acid/amoxicillin, or enrofloxacin.

38. (New) A method of detecting the presence of urinary pathogens in a biological sample and of simultaneously determining the susceptibility of the urinary pathogens to antimicrobial agents, said method comprising:

providing a multicompartment assay device comprising:

at least one compartment comprising a medium capable of sustaining growth of total microbial organisms; at least one compartment comprising a uropathogenic specific medium comprising yeast extract; and, at least one compartment comprising an antimicrobial susceptibility interpretation medium;

placing a portion of the biological sample respectively in said at least one compartment comprising a medium capable of sustaining growth of total microbial organisms; said at least one compartment comprising a uropathogenic specific medium comprising yeast extract; and, said at least one compartment comprising an antimicrobial susceptibility interpretation medium comprising an antimicrobial agent;

whereby metabolism of a signal generating substrate and production of a detectable signal in said at least one compartment comprising a medium capable of

sustaining growth of total microbial organisms indicates the presence of microbial organisms in the sample; metabolism of a signal generating substrate and production of a detectable signal in said at least one compartment comprising a uropathogenic specific medium comprising yeast extract indicates the presence of urinary pathogens in the sample; and metabolism of a signal generating substrate and production of a detectable signal in said at least one compartment comprising an antimicrobial susceptibility interpretation medium indicates that the organisms lack susceptibility to the antimicrobial agent comprised in said antimicrobial susceptibility interpretation medium; and

examining the compartments to determine the presence of urinary pathogens in said biological sample and the susceptibility of said urinary pathogens to said antimicrobial agents.

39. (New) The method of claim 38, wherein the biological fluid is urine.

40. (New) The method of claim 39, wherein the urinary pathogens are primary gram negative urinary pathogens.

41. (New) The method of claim 40 wherein the primary gram negative urinary pathogens comprise *Enterobacteriaceae*.

42. (New) The method of claim 40 wherein the primary gram negative urinary pathogens are selected from the group consisting of: *Escherichia coli*, *Klebsiella spp.*, *Enterobacter spp.*, *Proteus mirabilis*, *Proteus vulgaris*, *Morganella morganii*, *Providencia retteri*, and *Acinetobacter spp.*

43. (New) The method of claim 38 wherein the at least one antimicrobial susceptibility interpretation medium comprises amoxicillin, clavulanic acid/amoxicillin, or enrofloxacin.